K041543

GE Healthcare

JUN 2 2 2004

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: GE Discovery ST

Submitter Information:

Name: GE Healthcare

Address: 3000 N. Grandview Blvd.
Waukesha, WI 53188

Registration Number: 2126677

Contact Information: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager

GE Healthcare
P.O. Box 414
Milwaukee, WI 53201

(262) 544-3894

Date Prepared: May 7, 2004

Device Classification

Classification Code: KPS
Classification Name: Emission Computed Tomography System
(per 21 CFR 892.1200)

and

Classification Code: JAK
Classification Name: Computed Tomography X-ray System
(per 21 CFR 892.1750)

Panel Identification: Radiology
Classification Class: Class II Product

Identification of Legally Marketed Equivalent Devices

Product Name: GE Discovery ST
510(k) #: K022872

Product Name: GE Discovery LS
510(k) #: K040172

General Electric Company
3000 N Grandview Blvd
Waukesha, WI 53188
U.S.A.

Device Description

The Discovery ST is an integrated multi-slice Computed Tomography and Positron Emission Tomography scanner. In addition to providing CT and PET stand-alone capabilities, it uses the CT images to correct for non-uniform attenuation of the PET images and it uses integrated CT and PET images to localize emission activity in the patient anatomy. Discovery ST has capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated user interface. It can also be used as a stand-alone head and whole body multi-slice computed tomography diagnostic imaging system.

Intended Use

The GE Discovery ST system is intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The Discovery ST is to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. This device can also assist in radiotherapy planning.

The Discovery ST system can also be used as a stand-alone head and whole body multi-slice computed tomography (CT) diagnostic imaging system.

Conclusion

In the opinion of GE Healthcare, the modified GE Discovery ST is substantially equivalent in terms of safety and effectiveness to the currently marketed GE Discovery ST, 510(k) number K022872, and GE Discovery LS, 510(k) number K040172.

General Electric Company
3000 N Grandview Blvd
Waukesha, WI 53188
U.S.A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

GE Healthcare
% Mr Tomas Borsai
Program Manager
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K041543
Trade/Device Name: GE Discovery ST
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: June 3, 2004
Received: June 8, 2004

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041543

Device Name: GE Discovery ST

Indications for Use:

The GE Discovery ST system is intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The Discovery ST is to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. This device can also assist in radiotherapy planning.

The Discovery ST system can also be used as a stand-alone head and whole body multi-slice computed tomography (CT) diagnostic imaging system.

Prescription Use ✓ (21 CFR 801 Subpart D)

~~AND~~/OR

Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041543